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09/694,293	10/23/2000	Stephen T. Kuehn	S16.12-0101	1653

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EXAMINER

NGUYEN, VI X

ART UNIT

PAPER NUMBER

3731

DATE MAILED: 01/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/694,293

Applicant(s)

KUEHN ET AL.

Examiner

Victor X Nguyen

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 17-33 is/are rejected.
- 7) ☒ Claim(s) 16 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 October 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4,9.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

**DETAILED ACTION**

***Response to Amendment***

1. The amendment filed on November 5, 2002 under 37 CFR 1.131 has been considered and an action on the merits follows.

***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-13 are rejected under 35 U.S.C. 102 (e) as being anticipated by Oz et al (U.S.6,269,819).

Regarding claim 1, notes Oz et al Figures 8, 9, 18 and 19 read on a surgical instrument comprising at-least one pair of arms (52), wherein the arms (52) sized and adapted for two adjacent heart valve leaflets (56); and wherein the arms (52) pivot from one orientation to a gripping position with ends of the pair arms being directed toward each other.

Regarding claims 2 and 3, notes Oz et al Figs 8, 9, 18 and 19 read on a surgical instrument, wherein the arms (52) flex to a core, wherein the surgical instrument has a gripping position (58), and wherein one of the arms (52) includes a projection for gripping a valve

Regarding claims 4 and 5, notes Oz et al Figs 8, 9, 18 and 19 read on a kit having a

Art Unit: 3731

catheter (50), a fastener applicator (44). The catheter (50) has a suitable dimension for deployment and insertion into a human heart. Furthermore, the pair arms (50) comprise the gripping elements (58).

Regarding claims 6, 7, notes Oz et al Figs 8, 9, 18 and 19 read on a kit, wherein a pair of arms (52) comprise a pointed tip and a clasp (not labeled) that engage each other in the gripping position (58). The arms (52) flex to a low position to fit within the catheter (50).

Regarding claims 8, 9, notes Oz et al Figs 8, 9, 18 and 19 read on a kit, wherein the surgical instrument comprises a shaft and a sleeve (not labeled) that slides over the shaft, wherein one member of the pair of arms (52) slides along the shaft with the sleeve (not labeled) engaging the sliding arms (52) to constrain their movement along the shaft. The arms (52) can slide along the shaft between a low position for fitting within the catheter (50).

Regarding claims 10, 11, notes Oz et al Figs 8, 9, 18 and 19 read on a kit, wherein the arms (50) pivot between a low position and an unconstrained extended position. The fastener applicator (44) comprises a shaft and the fastener (44) holds the leaflet fastener on the shaft.

Regarding claims 12, 13, notes Oz et al Figs 8, 9, 18 and 19 read on a kit, wherein the fastener applicator (44) comprises a shaft and a latch that releasably holds the surgical device on the shaft. The kit comprises a catheter (50), a fastener applicator (44). The catheter (50) has a suitable dimension for deployment and insertion into a human heart .

The functional language drawn to intended use, "Capable of fastening two adjacent leaflets" can not serve to distinguish over the prior art which includes all of the structural elements called for in the claims and can thus inherently perform in the same manner as the claim invention.

Claims 14, 15 and 17 are rejected under 35 U.S.C. 102 (b) as being anticipated by Bergman et al (U.S. 5,181,919).

Regarding claim 14, note Bergman Figs 1,2,3 read on a surgical device (10) comprising a ring (col 1, lines 6-30) and an applicator (col 1, lines 1-55), wherein the ring (col 1, lines 6-30) comprises two pointed shafts (16, 17) and wherein the applicator (col 1, lines 1-55) can apply a force to the ring (col 1, lines 6-30) to deform the ring (col 1, lines 6-30) to bring the points of the shafts (16, 17) toward each other. The ring (col 1, lines 6-30) and the applicator (col 1, lines 1-55) have an appropriate size for placement within a chamber of a human heart (col 1, lines 1-57).

Regarding claim 15, note Bergman Figs 1,2,3 read on a surgical device (10), wherein the ring (col 1, lines 6-30) comprises a curved tube (11, col 6, lines 4-22) extending from one pointed shaft (16, 17) into which the second pointed shaft (16, 17) extends.

Regarding claim 17, note Bergman Figs 1,2,3 read on a surgical device (10), wherein the two pointed shaft (16, 17) extend from a notch that is a weak point at which the ring (col 1, lines 6-30) can be deformed to direct the pointed shafts (16, 17) toward each other.

Claims 18-22, 24-29 are rejected under 35 U.S.C. 102 (b) as being anticipated by King et al (U.S. 3,874,388).

Regarding claim 18, note King Figs 7, 9b and 15b read on an instrument comprising a shaft (2 is considered a shaft), a cap (84), a gripper (91) and a flexible rod (3 is considered a rod), wherein the gripper (91) comprises a plurality of arms (7) radiating from a pivot (84, 294) with each arm (7) having a spike, wherein the cap (84) is located distal to the pivot (84, 294) and the pivot (84, 294) is located distal to the shaft (2), and wherein the flexible rod (3) connects to the cap (84) to provide for movement of the cap (84) relative to the gripper (91) and the shaft (2).

Art Unit: 3731

by pulling the flexible rod (3). The cap (84) has an opening that can be inserted over the pivot (84, 294) to lock the arms (7) in a closed position.

Regarding claims 19, 20, note King Figs 7, 9b and 15 b read on an instrument, wherein the arms (7) connected by a resilient web (col 6, lines 31-54), wherein the pivot (84, 294) is formed from the spring metal (col 7, lines 59-68; col 8, lines 1-7).

Regarding claims 21, 22, note King Figs 7, 9b and 15b read on an instrument, wherein the arms (7) comprises two pairs of arms, wherein the pairs of arms (7) are connected by a resilient web (col 6, lines 31-54), and wherein the web (col 6, lines 31-54) is covered with fabric (col 6, lines 49-68).

Regarding claims 25, 26, note King Figs 7, 9b and 15b read on an instrument, wherein the pivot (84, 294) comprises a hinge (col 6, lines 14-50), wherein the hinge (col 6, lines 14-50) comprises a spring (col 6, lines 14-50; col 8, lines 1-18).

Regarding claim 27, note King Figs 7, 9b and 15b read on an instrument, wherein the arms (7) are biased to an extended position due to the forces at the pivot (84, 294) and further comprising strands (col 8, lines 36-67) connect the shaft (2) with the arms.

Regarding claims 28, 29 note King Figs 7, 9b and 15b read on an instrument, wherein the rod (3) has a disengaging mechanism that connects the cap (84) to the rod (3). The cap (84) comprises a ridge (291, 291') and the gripper (91) comprise a bump (col 8, lines 19-68) positioned to engage the ridge (291, 291') in the locked position.

Regarding claim 30, note King Figs 7, 9b and 15b read on an instrument comprising a cap (84) and a gripper (91) comprises a plurality of arms (7) radiating from a pivot (84, 294),

Art Unit: 3731

wherein each arm has a spike, and wherein the pivot (84, 294) is inserted within an opening in the cap (84) to lock the arms (7).

Regarding claims 31, 32 note King Figs 7, 9b and 15b read on an instrument, wherein the cap (84) comprises a locking mechanism that engages the gripper (91) in a locked position. The cap (84) comprises a slot (col 7, lines 60-68, col 8, lines 1-7), and wherein the gripper (91) is held by the stops within the slot (col 7, lines 60-68, col 8, lines 1-7) such that the gripper (91) can slide within the slot to alter the extension of the gripper with the stops to prevent the separation of the cap and the gripper (91).

Regarding claim 33, note King Figs 7, 9b and 15b read on an instrument, wherein the rod (3) has a disengaging mechanism that permits the rod (3) to releasably hold the cap (8, fig 8).

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 23 is rejected under 35 U.S.C. 103 (a) as being unpatentable over King et al (3,874, 388).

King discloses the claimed invention except the memory metal comprises a nickel alloy.

It would have been obvious matter of design choice to disclose the memory metal comprises a nickel alloy, since the applicant has not disclosed that the useful of making the memory metal comprises a nickel alloy solves any stated problem or is for any

particular purpose and it appears that the invention would perform equally well with any equivalent material.

*Allowable Subject Matter*

2. Claim 16 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art of record disclose or suggest a spring within the tube between the pointed shafts and a releasable lock that can hold the second pointed shaft within the tube in a locked position.

*Response to Arguments*

Applicant's arguments filed 11/5/2002 have been fully considered but they are not persuasive. **Claims 1-33 are pending.**

Applicant's arguments with respect to claims 1-33 have been considered but are moot in view of the new ground (s) of rejection as discussed above.

Applicant's cooperation in correcting the informalities in the drawings and specification are appreciated. All of the objection to the specification as failing to provide proper antecedent basis for the claimed subject matter have been overcome. Applicant's cooperation in explaining the claims subject matter more specific to overcome the claim objections relating to indefinite claim language is also appreciated.

With regard to arguments on the rejection under 35 U.S.C. 102 (page 8-9), in regard to claims 18 and 30, King (U.S. Patent 3,874,388) does disclose an instrument (figs 7, 9b, 15b) having a cap (84) and a gripper (91) wherein the gripper comprises a plurality of arms (7)



radiating from a pivot; and wherein the opening in the cap (84) positioned over the pivot of the gripper locked the arms in a closed or collapsed gripping position (col. 9, lines 36-67).

Therefore, the rejection of claims 1 and 30 under 35 U.S.C. 102 (b) as being anticipated by King (U.S. Patent 3,874,388) is proper.

### *Conclusion*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victor X Nguyen whose telephone number is (703) 305-4898. The examiner can normally be reached on M-F (8-4.30 P.M).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on (703) 308-2496. The fax phone numbers for the

Art Unit: 3731


organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Victor X Nguyen  
Examiner  
Art Unit 3731

Vn

1/10/2003

  
**KEVIN T. TRUONG**  
**PRIMARY EXAMINER**

1/13/03